

### **REMARKS**

These remarks are in response to the Final Office Action mailed October 16, 2008. The specification has been amended to reflect the priority information and the current status of the parent application. Claims 33, 35 and 36 have been amended. The amendment to claim 33 is supported in original claim 33 and are made for purposes of antecedent basis and to clarify reference to regions of an antibody. Claims 35 and 36 have been amended to correct antecedent basis and make claim terms consistent throughout the claim set. No new matter is believed to have been introduced.

#### **I. EXAMINER-APPLICANT INTERVIEW**

Joseph R. Baker, Jr. (Counsel for Applicants) and Robin L. Teskin (Counsel for Licensee) respectfully thank Examiner Cook and Supervisor Shibuya for their time during the telephonic interview conducted on March 4, 2009. During the interview the parties discussed the pending rejection and more particularly the sequence information and deposit requirement.

The parties agreed that a deposit was not needed based upon the teachings of the disclosure. Furthermore, the parties agreed that minor amendments to the claims would be made and that such amendments would place the claims in condition for allowance. Examiner Shibuya indicated that the amendments were minor and did not change the scope. Accordingly, no further search would be necessary.

In addition Supervisory Examiner Shibuya advised that the Oath filed with the divisional application should be reviewed for informalities and a substitute Oath be provided if there are any noted informalities.

#### **II. REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH**

Claims 33-40 stand rejected under 35 U.S.C. §112, first paragraph as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In particular the Office

alleges that a deposit of biological material is necessary. Applicants respectfully traverse this rejection.

The Examiner and the Examiner's supervisor agreed during the telephonic interview that a deposit of biological material is not required. Accordingly, Applicants respectfully request withdrawal of the rejection.

Claims 33-40 stand rejected under 35 U.S.C. §112, first paragraph as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In particular, the Office alleges that the term "antibody fragment" does not include sequence information such that the structure of the fragment can be determined. Applicants respectfully traverse this rejection.

Applicants respectfully submit that the term "antibody fragment" refers to a "Fab", a structure and term well recognized in the art. An Fab comprises variable light and variable heavy regions/domains of an antibody (note that the term "variable" does not mean the sequence varies in a specific antibody). As the Examiner agreed during the telephonic interview, the claims and specification set forth the sequence of the variable light and variable heavy regions/domains of an antibody as well as their binding specificity. Applicants at the request of the Examiner have amended the claims to clarify the art-recognized term "fragment antibody". Applicants have amended claims 33 and 35 to correct the reference to "fragment antibody" to refer to "fragment antibody (Fab)". Applicants believe that the interview, the foregoing amendments and these remarks address the rejection. Accordingly, Applicants respectfully request withdrawal of the rejection.

Claims 33-40 stand rejected under 35 U.S.C. §112, first paragraph as allegedly failing to comply with the enablement requirement. In particular, the Office alleges that a nucleic acid encoded by the nucleic acid sequences recited in the claims generate multiple peptide sequences. Applicants respectfully traverse this rejection.

During the Interview the Examiner and the Examiner's Supervisor agreed that the nucleic acid sequence of SEQ ID NO:1 and SEQ ID NO:2 each do not encode a plurality of different polypeptides. Rather, the Examiner recognized that the domains referred to as the "variable chain" encoded by the recited sequence have a specific amino acid sequence. As discussed during the interview an antibody, monoclonal antibody, humanized antibody, Fab, or ScFv comprising the amino acid sequences encoded by SEQ ID NO:1 and 2 have the binding specificity recited in the claims. Furthermore, Applicants discussed that SEQ ID NO:1 and 2 each encode regions that provide the "working" portion of the antibody for antigen recognition (i.e., the "variable light chain" and "variable heavy chain"), the sequence of such chains encoded by SEQ ID NO:1 or 2 do not vary.

For at least the foregoing, the Applicant submits that the claimed invention is patentable and request reconsideration and notice of such allowable subject matter.

The Director is authorized to charge any required fee or credit any overpayment to Deposit Account Number 50-4586, please reference the attorney docket number above.

The Examiner is invited to contact the undersigned at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted,

GAVRILOVICH, DODD & LINDSEY LLP

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